

## **FDA STATEMENT**

# Joint CDC and FDA Statement on Johnson & Johnson COVID-19 Vaccine

The following statement is attributed to Dr. Peter Marks, director of the FDA's Center for Biologics Evaluation and Research and Dr. Anne Schuchat, Principal Deputy Director of the CDC

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#### Statement From:

Director - Center for Biologics Evaluation and Research (CBER) Peter Marks M.D., PhD.

As of April 12, more than 6.8 million doses of the Johnson & Johnson (Janssen) vaccine have been administered in the U.S. CDC and FDA are reviewing data involving six reported U.S. cases of a rare and severe type of blood clot in individuals after receiving the J&J vaccine. In these cases, a type of blood clot called cerebral venous sinus thrombosis (CVST) was seen in combination with low levels of blood platelets (thrombocytopenia). All six cases occurred among women between the ages of 18 and 48, and symptoms occurred 6 to 13 days after vaccination. Treatment of this specific type of blood clot is different from the treatment that might typically be administered. Usually, an anticoagulant drug called heparin is used to treat blood clots. In this setting, administration of heparin may be dangerous, and alternative treatments need to be given.

CDC will convene a meeting of the Advisory Committee on Immunization Practices (ACIP) on Wednesday to further review these cases and assess their potential significance. FDA will review that analysis as it also investigates these cases. Until that process is complete, we are recommending a pause in the use of this vaccine out of an abundance of caution. This is important, in part, to ensure that the health care provider community is aware of the potential for these adverse events and can plan for proper recognition and management due to the unique treatment required with this type of blood clot.

Right now, these adverse events appear to be extremely rare. COVID-19 vaccine safety is a top priority for the federal government, and we take all reports of health problems following COVID-19 vaccination very seriously. People who have received the J&J vaccine who develop severe headache, abdominal pain, leg pain, or shortness of breath within three weeks after vaccination should contact their health care provider. Health care providers are asked to report adverse events to the Vaccine Adverse Event Reporting System at <a href="https://vaers.hhs.gov/reportevent.html">https://vaers.hhs.gov/reportevent.html</a>.

CDC and FDA will provide additional information and answer questions later today at a media briefing. A <u>recording External Link Disclaimer</u> of that media call is available on the FDA's YouTube channel.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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### **COVID-19 Variants**

# What is a variant?

Viruses constantly change through mutation, and new variants of a virus are expected to occur over time.

## What we know:

Multiple variants of the virus that causes COVID-19 are circulating globally and within the United States. The CDC has 3 classifications of variants being monitored:

- Variant of Interest (VOI)
- Variant of Concern (VOC)
- Variant of High Consequences (VOHC)

There are currently 5 VOCs in the United States:

- **B.1.1.7**: This variant was first identified in the US in December 2020. It was initially detected in the UK.
- **B.1.351**: This variant was first identified in the US at the end of January 2021. It was initially detected in South Africa in December 2020.
- P.1: This variant was first detected in the US in January 2021. P.1 was initially identified in travelers from Brazil, who were tested during routine screening at an airport in Japan, in early January.
- B.1.427 and B.1.429: These two variants were first identified in California in February 2021 and were classified as VOCs in March 2021.

These variants seem to spread more easily and quickly than other variants, which may lead to more cases of COVID-19. An increase in the number of cases will put more strain on health care resources, lead to more hospitalizations, and potentially more deaths.

So far, studies suggest that antibodies generated through vaccination with currently authorized vaccines recognize these variants. This is being closely investigated and more studies are underway.

## What We Do Not Know:

Public health officials are studying these variants quickly to learn more about how to control their spread. They want to understand whether the variants:

- Spread more easily from person-to-person
- Cause milder or more severe disease in people
- Are detected by currently available viral tests
- Respond to medicines currently being used to treat people for COVID-19
- Change the effectiveness of COVID-19 vaccine

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## Variants in Arizona:

Researchers have found a new COVID variant that started right here in Arizona. What they found in the data is concerning, and all the more reason why doctors say getting to herd immunity in Arizona is so important.

The ASU Biodesign Institute found the new COVID variant stemming from cases in Arizona.

"It was a unique variant. Is that the best news for us? No," said emergency medicine doctor Frank Lovecchio. "It turns out this variant does not work as well against the vaccines and against the other therapies that we have."

Dr. Lovecchio said that part makes this even more difficult as it starts to become more widespread.

According to the study by the ASU researchers, there have been 17 cases detected: 15 in Arizona. In Arizona alone, the cases were discovered between February 1 and March 2.

But with the researchers writing in the study, this variant is "poised to emerge," and it's something doctors are taking very seriously. Even though this variant shows resistance to the vaccine, doctors said the more people who get the vaccine, the better off we are. Once more people are protected, the virus spread is much lower, and then it can't live to keep mutating.

Rigorous and increased compliance with public health mitigation strategies, such as vaccination, physical distancing, use of masks, hand hygiene, and isolation and quarantine, is essential to limit the spread of the virus that causes COVID-19 and protect public health.

### References:

https://www.cdc.gov/coronavirus/2019-ncov/variants/index.html

https://www.azfamily.com/news/continuing\_coverage/coronavirus\_coverage/asu-researchers-discover-new-covid-variant-in-arizona/article\_2bb078aa-91c8-11eb-b0fc-bbc2461022d7.html